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(54) **Nutrition for elderly patients**

Nahrung für alte Patienten

Nutrition pour patients âgés

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(56) References cited:  
**EP-A- 0 486 425**                      **EP-A- 0 614 616**  
**WO-A-88/01861**                      **WO-A-94/27628**  
**WO-A-94/28734**                      **US-A- 5 085 883**  
**US-A- 5 221 668**

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## Description

[0001] This invention relates generally to compositions and their use for the nutritional support of patients. More specifically, this invention relates to nutrition for elderly patients.

[0002] Americans greater than 65 years old were, at the turn of the century, 4% of the population; currently, they are greater than 12% of the population. Though only 12% of the population, the elderly account for greater than 40% of acute hospital bed days, buy greater than 30% of all prescription drugs and spend 30% of the greater than 600 billion dollar US health budget. Still further, it is estimated that in 2030, greater than 70 million Americans (1:5) will be over the age of 65, and the "over 85's" are expected to experience the highest percentage increase of all. The Merck Manual, 16th Edition, p. 2540.

[0003] As the average age of the population increases, obtaining a better understanding of the unique aspects of ageing in relation to nutritional needs and treatment is imperative. Many physiologic functions decline progressively throughout adult life and have an impact on nutrition. For instance, a reduction in the number of functioning cells and the resultant slowing of metabolic processes results in a decrease in caloric requirements among the elderly. Also, the reduction in physical activity that generally accompanies ageing further decreases energy requirements.

[0004] Merely decreasing the total caloric intake of an elderly patient may adversely affect the required nutrition of the patient. When the total caloric intake is reduced, the remaining food intake must carefully insure a properly balanced intake of proteins, vitamins and minerals. To reduce caloric intake in the elderly, consumption of "empty" calories (i.e. fats) must be reduced and consumption of nutrient-dense foods (i.e. carbohydrates and proteins) must be increased.

[0005] While the nutritional needs of the mature adult patient differ from adult patients, in the health care settings, standard nutritional formulas are the primary form of elemental nutrition currently being used for the elderly. Naturally, standard formulas do not take into account the known nutritional needs of the elderly patients. These standard nutritional products must be supplemented with key micronutrients to compensate for common deficiencies and metabolic changes of the elderly patient. Moreover, since the elderly have a diminished capacity to manage a fluid load, standard formulas must be modified to produce a calorically dense formulation that will provide increased energy and nutrition with a minimum amount of fluid.

[0006] WO88/01861 (Baxter Travenol Laboratories Inc) discloses an enteral or parenteral nutritional composition for individuals under treatment for or at risk of atherosclerotic, vascular, cardiovascular, and/or thrombotic disease. The composition comprises a protein source, a carbohydrate source, and at least one lipid selected from gamma-linolenic acid, eicosapentaenoic acid, docosahexaenoic acid, sterodonic acid, and linolenic acid. The protein source preferably provides 15 to 25% of the caloric content of the composition.

[0007] US5221668 (Abbott Laboratories) discloses a liquid nutritional product for trauma and surgery patients. The product has a caloric density of about 5.0 to 6.3 kJ/ml (1.2 to 1.5 kcal/ml). It is disclosed that about 18-24% of calories are provided by protein, about 20-30% of calories are provided by lipids and about 46-62% of the calories are provided by carbohydrates. The product can include dietary fibre.

[0008] US5085883 (Abbott Laboratories) discloses a blend of dietary fibre which can be included in the product of US5221668. The blend includes 5 to 50% of a dietary fibre which is both soluble and fermentable; 5% to 20% of a dietary fibre which is both soluble and non-fermentable; and 45% to 80% of a dietary fibre which is both insoluble and non-fermentable.

[0009] EP0486425 (Sandoz Nutrition Ltd) discloses a liquid oral nutritional formulation comprising 40-90% of calories as carbohydrate, 2-30% of calories as protein and 0-35% of calories as fat, and from 0-17% of calories as fibre, whereby the protein source is for at least 60% by weight whey protein concentrate and the pH of the formulation is from 3.5-3.9. The protein source may include whey, caseinate, soy protein and / or egg whites. Whey is preferred because of its good flavour and solubility at low pH. It is disclosed that caseinate, soy protein and egg white may be used provided at least 60% of the dietary nitrogen source is whey. In addition, at concentrations above 40%, caseinate and soy protein tend to precipitate and impart poor taste.

[0010] Therefore, a need exists for a nutritional formula designed to meet the nutritional needs of elderly patients.

[0011] In one aspect, this invention provides the use of nutritional composition in the manufacture of a medicament for the treatment or prevention of protein-energy malnutrition in an elderly patient wherein the nutritional composition comprises a protein source for providing at least 18% of the total calories of the composition, a carbohydrate source; a source of dietary fibre having a soluble to insoluble fibre ratio of 1:4 to 4:1, and a lipid source including a mixture of medium and long chain triglycerides.

[0012] In a further aspect, this invention provides a composition for providing nutrition to an elderly patient; the composition comprising:

caseinate in an amount to provide at least 18% of the total calories of the composition;  
a carbohydrate source in an amount to provide 48 % to 55 % of the total calories of the composition and which includes a source of dietary fibre having a soluble fiber to insoluble fiber ratio of 1:4 to about 4:1 (preferably about

1:3); and

a lipid source in an amount to provide 26% to 36% of the total calories of the composition and including a mixture of medium and long chain triglycerides; 2 to 10mg/l of  $\beta$ -carotene; and vitamins and minerals to meet or exceed the US RDA; the composition having an energy density of 5 kJ/ml (1.2 kcal/ml).

**[0013]** An advantage of the composition is that it is ready-to-use, nutritionally complete, and contains proteins, lipids, carbohydrates and vitamins and minerals in proportions appropriate for elderly patients.

**[0014]** Moreover, an advantage of the composition is that it provides a nutritional diet for tube and oral use designed for optimal tolerance and absorption in elderly patients.

**[0015]** Another advantage of the composition is that it contains higher levels of key micronutrients to compensate for common deficiencies and metabolic changes in elderly when compared with standard formulas.

**[0016]** Furthermore, an advantage of the composition is that it eliminates the need for vitamin supplementation and meets regulatory requirements of the elderly.

**[0017]** Yet another advantage of the composition is that it includes an ideal fiber balance to promote good bowel function in ageing patients. More specifically, the ideal fiber level avoids constipation and prevents impaction.

**[0018]** Still another advantage of the composition has increased protein levels to account for the increased needs often found in the institutionalized elderly. The composition addresses the increased repletion requirements for protein-energy malnutrition in the older patient.

**[0019]** Moreover, an advantage of the composition is that it provides a calorically dense formulation that allows for increased energy and nutrition with a minimal amount of fluid. Uniquely, the composition meets or exceeds U.S. RDA for vitamin and minerals in one liter. As a result, the composition is appropriate for fluid-restricted patients and is designed to accommodate slower gastric emptying, which may be seen in the elderly.

**[0020]** Additional features and advantages of the present invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments.

**[0021]** Preferably, with respect to the use according to the present invention, the nutritional composition meets or exceeds the US RDA for vitamins and minerals in one litre.

**[0022]** Preferably, according to the present invention, the composition includes a source of  $\beta$ -carotene.

**[0023]** Preferably, according to the present invention, the composition has a caloric density of approximately 5 kJ/ml (1.2 kcal/ml).

**[0024]** Preferably, with respect to the use or the nutritional composition according to the present invention, the composition includes the following vitamins and minerals:

Vitamin C	120 to 300 mg/l
Zinc	15 to 30 mg/l
Vitamin D	400 to 800 mg/l
Vitamin E	60 to 180 mg/l
Vitamin A	3000 to 6000 IU/l
Folic acid	400 to 1600 mg/l
Vitamin B <sub>6</sub>	2 to 8 mg/l
Vitamin B <sub>12</sub>	6 to 18 mg/l
Thiamine	1.5 to 3 mg/l
Riboflavin	1.7 to 3.5 mg/l
Calcium	800 to 1600 mg/l
Selenium	50 to 150 mg/l

**[0025]** These are key vitamin and minerals found to be deficient in the institutionalized elderly.

**[0026]** Preferably, the use or the composition according to the present invention provides a composition which contains 8 g/l to 15 g/l of dietary fibre.

**[0027]** Preferably, the carbohydrate source according to the use or the composition of the present invention includes a source of a dietary fibre having a soluble fibre to insoluble fibre ratio of approximately 1:3.

**[0028]** Preferably, the use or the composition of the present invention provides that the long chain tryglycerides are selected to provide a ratio of n-6 to n-3 fatty acids of 4:1 to 10:1. N-6 and n-3 refer to omega-6 and omega-3 fatty acids, respectively.

**[0029]** Preferably, the carbohydrate source provides 48% to 55% of the total calories of the composition. More preferably, the soluble fiber constitutes approximately 30% of the dietary fiber source.

**[0030]** Preferably, lipid source provides about 26% to about 36% of the total calories of the composition.

**[0031]** In use, an effective amount of the composition is administered to an elderly patient.

**[0032]** Nutritional support of elderly requires prevention, recognition and treatment of nutritional depletion that may occur with ageing and illness. The composition and methods of this invention are designed specifically to provide nutritional support to elderly patients. In this regard, the composition is designed to meet the energy needs of an elderly patient in a reduced volume.

**[0033]** The protein source of the composition provides at least 18% of the total calories of the composition. In an embodiment, the protein source is caseinate. Relative to calorie needs, the elderly patient needs an increased amount of protein. Therefore, the composition includes slightly higher protein levels than standard formulas to account for increased needs often found in the institutionalized elderly.

**[0034]** The inventors believe that the increased protein in the composition helps correct the protein-energy malnutrition often found in elderly patients. The higher intake of protein may correct immunologic deficiencies associated with protein depletion. Moreover, the higher intake may prevent skin breakdown, which is highly correlated with protein depletion. Still further, the higher protein level promotes more rapid restoration of body protein stores that decrease with age.

**[0035]** Carbohydrates provide approximately 48% to 55% of the caloric content of the composition. In an embodiment, a carbohydrate source provides approximately 52% of the caloric content of the composition. Carbohydrates are an important energy source for the elderly patient as they are readily absorbed and utilized. A number of carbohydrates can be used including maltodextrin or sucrose.

**[0036]** In addition to simple sugars, the carbohydrate source includes a source of dietary fiber. Numerous types of dietary fiber are available. Dietary fiber passes through the small intestine undigested by enzymes and represents a kind of natural and necessary laxative. Suitable sources of dietary fiber, among others, include soy, oat or gum arabic.

**[0037]** The total fiber contained in the composition is approximately 8 to 15 g/l. While fiber is necessary for the elderly population since constipation is a chronic problem, the composition contains less total fiber than other products to alleviate problems associated with impaction and the increased water requirements associated with high amounts of fiber. Some older adults may not easily tolerate large amounts of fiber without adaptation. In fact, patients on narcotics or with ultramotility may be at risk for bowel obstruction, especially with the administration of excess fibers. Moreover, high fiber intake may bind calcium, reducing absorption; particularly given the high incidence of atrophic gastritis in the elderly. In a preferred embodiment, the composition includes approximately 10 g/l of total fiber.

**[0038]** The dietary fiber is a mixture of soluble and insoluble fiber. The inventors believe that a mixture of soluble and insoluble fibers may prevent or reduce constipation and lower serum cholesterol and blood glucose in the elderly. The soluble to insoluble ratio of the composition is approximately 4:1 to 1:4. In a preferred embodiment, the soluble to insoluble fiber ratio is approximately 1:3.

**[0039]** In the soluble/insoluble mixture, soluble fiber provides gut fuel by providing short chain free fatty acids in the large intestine. Additionally, the inventors believe that soluble fiber retains moisture. As a result thereof, while the total amount of fiber provided by the composition is less than other standard products, the amount of soluble fiber provided is higher.

**[0040]** The lipid source of the composition includes a mixture of medium chain triglycerides (MCT) and long chain triglycerides (LCT). The lipid source provides is approximately 26% to about 36% of the caloric content of the composition. In an embodiment, the lipid source provides approximately 30% of the caloric content of the composition.

**[0041]** The lipid source includes at least 20% from medium chain triglycerides. Such medium chain triglycerides are easily absorbed and metabolized in the elderly patient's body. The remainder of the lipid source is a mixture of long chain triglycerides. Suitable sources of long chain triglycerides are canola oil, corn oil, soy lecithin and residual milk fat. The lipid profile containing such long chain triglycerides is designed to have a polyunsaturated fatty acid omega-6 (n-6) to omega-3 (n-3) ratio of approximately 4:1 to 10:1. The proposed ratio of n-6:n-3 is designed to prevent suppression of the immune system caused by excessive n-6 fatty acids.

**[0042]** In an embodiment, the composition includes a source of beta-carotene. Beta-carotene meets a portion of the required vitamin A, thereby meeting micronutrient requirements in a small caloric volume. It is also an important nutrient with anti-oxidant properties. For example, it may reduce or mitigate symptoms of heart disease in ageing adults. Adequate amounts of beta-carotene may also protect against cataracts. The composition preferably includes approximately 2 to 10 mg/l of beta-carotene. In an embodiment, beta-carotene is present in an amount of approximately 6 mg/l.

**[0043]** Still further, the composition, in an embodiment, includes a specialized vitamin and mineral profile. The composition includes at least 100% of the USRDA of all vitamins and minerals. Moreover, the composition includes higher levels of the key vitamins and minerals found to be deficient in the institutionalized elderly. Vitamin-mineral deficiencies are often associated with protein-energy malnutrition in the elderly. The increased levels of vitamins and minerals exceed U.S. RDA (for normal, healthy adults) to meet the enhanced needs of the geriatric adults. As a result, utilizing the composition eliminates the need for vitamin and mineral supplementation.

**[0044]** Specifically, the composition preferably includes increased levels of vitamin C, zinc, vitamin D, vitamin E, vitamin A, folic acid, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, thiamine, riboflavin, calcium, and selenium.

**[0045]** Vitamin C is preferably present in an amount of approximately 120 to 300 mg/l. Blood levels of vitamin C tend to decline with age. In fact, greater than 40% of elderly may take in less than half of the U.S. RDA for vitamin C. Even mild deficiencies may play a role in the pathogenesis of declining neurocognitive function in ageing adults. Increased doses may be associated with increased immune function and exert a protective effect against cancer, heart disease and cataracts. In an embodiment, vitamin C is present in an amount of approximately 240 mg/l.

**[0046]** Zinc is necessary to maintain skin integrity, rate of epithelialization and collagen strength. Since intake and intestinal absorption decrease with age, low serum levels have been documented in the elderly. Supplementation with adequate zinc has been shown to restore immune function. The composition includes from approximately 15 to 30 mg/l of zinc. In an embodiment, zinc is present in an amount of approximately 24 mg/l.

**[0047]** Vitamin D is necessary for adequate phosphorous absorption. Likewise, calcium absorption is impaired in the elderly and higher levels of vitamin D help with absorption and decrease hyperthyroidism. Still further, a deficiency of vitamin D caused by lack of sun exposure may be common in the institutionalized elderly. Moreover, current RDA of the vitamin may be too low for the elderly to maintain serum parathyroid hormone concentrations and healthy bone mass. The composition includes from approximately 400 to 800 IU/l of vitamin D. In an embodiment, vitamin D is present in approximately 600 IU/l.

**[0048]** Vitamin E acts as an antioxidant and may protect against age-related accumulation of free-radical reactions and greater lipid peroxidation that may contribute to degeneration and disease. Supplementation with vitamin E has been shown to enhance cell-mediated immunity in the elderly. The composition includes from approximately 60 to 180 IU/l of vitamin E. In an embodiment, vitamin E is present in an amount of approximately 100 IU/l.

**[0049]** The amount of vitamin A, also an antioxidant, is increased as compared with other similar formulas. Vitamin A acts as a free radical scavenger and is present in the composition in approximately 3000 to 6000 IU/l. In an embodiment, vitamin A is present in approximately 4000 IU/l.

**[0050]** Vitamin B<sub>6</sub> and folic acid are at increased levels because vitamin B<sub>6</sub> and folic acid absorption in the elderly is inefficient. Also, there is a high degree of deficiency of these in the elderly population. In fact, vitamin B<sub>6</sub> deficiency has been associated with neurological changes and immunocompetence in the elderly. The composition includes from approximately 2 to 8 mg/l of vitamin B<sub>6</sub> and approximately 400 to 1600 mg/l of folic acid. In an embodiment, vitamin B<sub>6</sub> and folic acid are present in amounts of approximately 4 mg/l and 1200 mg/l, respectively.

**[0051]** Vitamin B<sub>12</sub> is at an increased level in the composition due to deficiencies in the elderly from atrophic gastritis and impaired absorption. Serum B<sub>12</sub> is known to decline with age. The composition includes from approximately 6 to 18 mg/l of vitamin B<sub>12</sub>. In an embodiment, vitamin B<sub>12</sub> is present in an amount of approximately 12 mg/l.

**[0052]** Thiamine (B<sub>1</sub>) transmits impulses for central and peripheral nerve cell function. Decreased intake of thiamine may be associated with neuromuscular malfunctions and heart failure. The composition includes from approximately 1.5 to 3 mg/l of thiamine. In an embodiment, thiamine is present in an amount of approximately 2.25 mg/l.

**[0053]** Adequate amounts of riboflavin (B<sub>2</sub>), the level of which is also increased in the composition, are required for proper energy and protein utilization. Deficiency of riboflavin may result in skin breakdown. The composition includes from approximately 1.7 to 3.5 mg/l of riboflavin. In an embodiment, riboflavin is present in an amount of approximately 2.55 mg/l.

**[0054]** As stated above, calcium absorption is impaired in the elderly. Thus, increased levels of calcium are included in the composition of the present invention. Calcium is required for tissue repair. Moreover, calcium is important in slowing/preventing bone loss in postmenopausal osteoporosis. Increased intake may be required for adequate calcium balance. The composition includes from approximately 800 to 1600 mg/l of calcium. In an embodiment, calcium is present in an amount of approximately 1250 mg/l.

**[0055]** Still further, selenium is at an increased level in the composition. Selenium acts as an anti-oxidant and an immune stimulant. It also has some antiinflammatory action. The composition includes from approximately 50 to 150 mg/l of selenium. In an embodiment, selenium is present in an amount of approximately 80 mg/l.

**[0056]** The composition is a ready-to-use enteral formulation. The composition can be used as a supplement or for total enteral nutritional support. The composition can be tube-fed to a patient, or fed by having the patient drink it. Preferably, the caloric density of the composition is 5.0 kJ/ml (1.2 kcal/ml) and yields a non-protein calorie-to-nitrogen ratio of 114:1 to promote positive nitrogen balance.

**[0057]** By way of example, and not limitation, an example of a suitable composition that may be used is as follows:

**[0058]** The composition includes the following ingredients: protein: caseinate; carbohydrate: maltodextrin; fat: canola oil, corn oil, soy lecithin, and residue milk fat; dietary fiber; water; vitamin A; beta-carotene; vitamin D; vitamin E; vitamin K; vitamin C; thiamine (B<sub>1</sub>); riboflavin (B<sub>2</sub>); niacin; vitamin B<sub>6</sub>; folic acid; pantothenic acid; vitamin B<sub>12</sub>; biotin; choline; taurine; carnitine; calcium; phosphorus; magnesium; zinc; iron; copper; manganese; iodine; sodium; potassium; chloride; chromium; molybdenum; and selenium.

**[0059]** The composition has the following nutrient composition (per 5016 Joules (1200 calories)):

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Nutrient Composition	Amount	% U.S. RDA*
Protein	54 g	120
Carbohydrate	156 g	**
Fat***	40.6 g	**
Dietary Fiber	10	**
Water	742 ml	**
Vitamin A	4000 IU	280****
Beta-Carotene	6 mg	**
Vitamin D	600 IU	150
Vitamin E	100 IU	333
Vitamin K	0.080 mg	**
Vitamin C	240 mg	400
Thiamine (B <sub>1</sub> )	2.25 mg	150
Riboflavin (B <sub>2</sub> )	2.55 mg	150
Niacin	40 mg	200
Vitamin B <sub>6</sub>	4 mg	200
Folic Acid	1.2 mg	300
Pantothenic Acid	15 mg	150
Vitamin B <sub>12</sub>	0.012 mg	200
Biotin	0.400 mg	133
Choline	452 mg	**
Taurine	100 mg	**
Carnitine	100 mg	**
Calcium	1250 mg	125
Phosphorus	1000 mg	100
Magnesium	400 mg	100
Zinc	24 mg	160
Iron	18 mg	100
Copper	2 mg	100
Magnesium	4 mg	**
Iodine	0.15 mg	100
Sodium	763 mg	**
Potassium	1560 mg	**
Chloride	1296 mg	**
Chromium	0.10 mg	**
Molybdenum	0.15 mg	**

\* U.S. Recommended Daily Allowance for Adults and Children 4 or More Years of Age

\*\* U.S. RDA Not Established.

\*\*\* MCT Provides 8.12 Grams

\*\*\*\* Vitamin A Calculated As a Combination of Retinol (80% of U.S. RDA per 1000 ml) Plus Beta-Carotene. Conversion of Beta-Carotene to Retinol Occurs in the Body Up to a Maximum of 10,000 IU per 100 ml (200% of U.S. RDA).

(continued)

Nutrient Composition	Amount	% U.S. RDA*
Selenium	0.08 mg	**

\* U.S. Recommended Daily Allowance for Adults and Children 4 or More Years of Age

\*\* U.S. RDA Not Established.

**Claims**

1. Use of a nutritional composition in the manufacture of a medicament for the treatment or prevention of protein-energy malnutrition in an elderly patient wherein the nutritional composition comprises a protein source for providing at least 18% of the total calories of the composition, a carbohydrate source; a source of dietary fibre having a soluble fibre to insoluble fibre ratio of 1:4 to 4:1, and a lipid source including a mixture of medium and long chain triglycerides.
2. Use according to claim 1 wherein the nutritional composition meets or exceeds the US RDA for vitamins and minerals in one litre.
3. Use according to claim 1 or 2 in which the composition includes a source of beta-carotene.
4. Use according to any preceding claim in which the composition has a caloric density of approximately 5 kJ/ml (1.2 kcal/ml).
5. A nutritional composition for providing nutrition to an elderly patient; the composition comprising:
 

caseinate in an amount to provide at least 18% of the total calories of the composition;  
 a carbohydrate source in an amount to provide 48% to 55% of the total calories of the composition and which includes a source of dietary fibre having a soluble fiber to insoluble fiber ratio of 1:4 to 4:1; and  
 a lipid source in an amount to provide 26% to 36% of the total calories of the composition and including a mixture of medium and long chain triglycerides;  
 2 to 10mg/l of  $\beta$ -carotene; and  
 vitamins and minerals to meet or exceed the US RDA;  
 the composition having an energy density of 5 kJ/ml (1.2 kcal/ml).
6. Use according to any one of claims 1 to 4 or a composition according to claim 5 in which the composition includes the following vitamins and minerals:

Vitamin C	120 to 300 mg/l
Zinc	15 to 30 mg/l
Vitamin D	400 to 800 mg/l
Vitamin E	60 to 180 mg/l
Vitamin A	3000 to 6000 IU/l
Folic acid	400 to 1600 mg/l
Vitamin B <sub>6</sub>	2 to 8 mg/l
Vitamin B <sub>12</sub>	6 to 18 mg/l
Thiamine	1.5 to 3 mg/l
Riboflavin	1.7 to 3.5 mg/l
Calcium	800 to 1600 mg/l
Selenium	50 to 150 mg/l.

7. Use according to any one of claims 1 to 4 or 6 or a composition according to claim 5 or 6 in which the nutritional composition contains 8 g/l to 15 g/l of dietary fibre.
8. Use according to any one of claims 1 to 4, 6 or 7 or a composition according to any one of claims 5 to 7 in which the carbohydrate source includes a source of dietary fiber having a soluble fiber to insoluble fiber ratio of approx-

imately 1:3.

9. Use according to any one of claims 1 to 4, 6, 7 or 8 or a composition according to any one of claims 5 to 8 in which the long chain triglycerides are selected to provide a ratio of n-6 to n-3 fatty acids of 4:1 to 10:1.

#### Patentansprüche

1. Verwendung einer Nahrungsmittelzusammensetzung bei der Herstellung eines Medikaments zur Behandlung oder Verhinderung von Proteinenergie-Mangelernährung in einem älteren Patienten, wobei die Nahrungsmittelzusammensetzung eine Proteinquelle umfasst, um mindestens 18 % der Gesamtkalorien der Zusammensetzung bereitzustellen, eine Kohlenhydrat-Quelle, eine Quelle an Nahrungsmittel-Fasern mit einem Verhältnis von löslichen Fasern zu unlöslichen Fasern von 1 : 4 bis 4 : 1, und eine Fettquelle einschließlich ein Gemisch von Triglyceriden mit mittlerer und langer Kettenlänge.

2. Verwendung nach Anspruch 1, wobei die Nahrungsmittelzusammensetzung den US RDA für Vitaminen und Mineralien in einem Liter genügt oder diese übertrifft.

3. Verwendung nach Anspruch 1 oder 2, wobei die Zusammensetzung eine  $\beta$ -Karotinquelle beinhaltet.

4. Verwendung nach einem der vorhergehenden Ansprüche, wobei die Zusammensetzung eine kalorische Dichte von annähernd 5 kJ/ml (1,2 kcal/ml) aufweist.

5. Nahrungsmittelzusammensetzung zur Bereitstellung von Nahrung für einen älteren Patienten, wobei die Zusammensetzung umfasst:

Kaseinat in einer Menge, um mindestens 18 % der Gesamtkalorien der Zusammensetzung zu liefern, eine Kohlenhydratquelle in einer Menge, um 48 % bis 55 % der Gesamtkalorien der Zusammensetzung zu liefern, und welche eine Quelle an Nahrungsmittel-Fasern mit einem Verhältnis von löslichen Fasern zu unlöslichen Fasern von 1: 4 bis 4 : 1 aufweist, und eine Fettquelle in einer Menge, um 26 % bis 36 % der Gesamtkalorien der Zusammensetzung bereitzustellen und einschließlich eines Gemisches von Triglyceriden mit mittlerer und langer Kettenlänge, 2 bis 10 mg/l  $\beta$ -Karotin, und Vitamine und Mineralien, um der US RDA zu genügen oder diese zu übertreffen,

wobei die Zusammensetzung eine Energiedichte von 5 kJ/ml (1,2 kcal/ml) aufweist.

6. Verwendung nach einem der Ansprüche 1 bis 4 oder eine Zusammensetzung nach Anspruch 5, wobei die Zusammensetzung die folgenden Vitamine und Mineralien enthält:

Vitamin C	120 bis 300 mg/l
Zink	15 bis 30 mg/l
Vitamin D	400 bis 800 mg/l
Vitamin E	60 bis 180 mg/l
Vitamin A	3000 bis 6000 IU/l
Folsäure	400 bis 1600 IU/l
Vitamin B <sub>6</sub>	2 bis 8 mg/l
Vitamin B <sub>12</sub>	6 bis 18 mg/l
Thiamin	1,5 bis 3,5 mg/l
Riboflavin	1,7 bis 3,5 mg/l
Calcium	800 bis 1600 mg/l
Selen	50 bis 150 mg/l.

7. Verwendung nach einem der Ansprüche 1 bis 4 oder 6 oder eine Zusammensetzung nach Anspruch 5 oder 6, wobei die Nahrungsmittelzusammensetzung 8 g/l bis 15 g/l an Nahrungsmittelfasern aufweist.



8. Verwendung nach einem der Ansprüche 1 bis 4, 6 oder 7 oder eine Zusammensetzung nach einem der Ansprüche 5 bis 7, wobei die Kohlenhydratquelle eine Quelle an Nahrungsmittelfasern mit einem Verhältnis von löslichen Fasern zu unlöslichen Fasern von etwa 1 : 3 umfasst.
9. Verwendung nach einem der Ansprüche 1 bis 4, 6, 7 oder 8 oder eine Zusammensetzung nach einem der Ansprüche 5 bis 8, wobei die langkettigen Triglyceride ausgewählt sind, um ein Verhältnis von n-6 zu n-3 Fettsäuren von 4 : 1 bis 10 : 1 bereitzustellen.

## Revendications

1. Utilisation d'une composition nutritionnelle dans la production d'un médicament pour le traitement ou la prévention d'une malnutrition en protéines-énergie chez un patient âgé, dans laquelle la composition nutritionnelle comprend une source de protéines destinée à fournir au moins 18 % des calories totales de la composition ; une source de glucides ; une source de fibres alimentaires ayant un rapport des fibres solubles aux fibres insolubles compris dans l'intervalle de 1:4 à 4:1 ; et une source de lipides comprenant un mélange de triglycérides à chaîne moyenne et à chaîne longue.
2. Utilisation suivant la revendication 1, dans laquelle la composition nutritionnelle répond au, ou excède, l'US RDA pour les vitamines et substances minérales dans un volume d'un litre.
3. Utilisation suivant la revendication 1 ou 2, dans laquelle la composition comprend une source de bêta-carotène.
4. Utilisation suivant l'une quelconque des revendications précédentes, dans laquelle la composition a une densité en calories d'approximativement 5 kJ/ml (1,2 kcal/ml).
5. Composition nutritionnelle destinée à assurer la nutrition d'un patient âgé ; composition comprenant :
- un caséinate en une quantité destinée à fournir au moins 18 % des calories totales de la composition ;
- une source de glucides en une quantité destinée à fournir 48 % à 55 % des calories totales de la composition et qui comprend une source de fibres alimentaires ayant un rapport des fibres solubles aux fibres insolubles compris dans l'intervalle de 1:4 à 4:1 ;
- une source de lipides en une quantité destinée à fournir 26 % à 36 % des calories totales de la composition et comprenant un mélange de triglycérides à chaîne moyenne et à chaîne longue ;
- 2 à 10 mg/l de bêta-carotène ; et
- des vitamines et substances minérales pour répondre au, ou excéder, l'US RDA ;
- la composition ayant une densité en énergie de 5 kJ/ml (1,2 kcal/ml).
6. Utilisation suivant l'une quelconque des revendications 1 à 4, ou composition suivant la revendication 5, dans laquelle la composition comprend les vitamines et substances minérales suivantes :

Vitamine C	120 à 300 mg/l
Zinc	15 à 30 mg/l
Vitamine D	400 à 800 mg/l
Vitamine E	60 à 180 mg/l
Vitamine A	3000 à 6000 UI/l
Acide folique	400 à 1600 mg/l
Vitamine B <sub>6</sub>	2 à 8 mg/l
Vitamine B <sub>12</sub>	6 à 18 mg/l
Thiamine	1,5 à 3 mg/l
Riboflavine	1,7 à 3,5 mg/l
Calcium	800 à 1600 mg/l
Sélénium	50 à 150 mg/l

7. Utilisation suivant l'une quelconque des revendications 1 à 4 ou 6 ou composition suivant la revendication 5 ou 6, dans laquelle la composition nutritionnelle comprend 8 g/l à 15 g/l de fibres alimentaires.

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8. Utilisation suivant l'une quelconque des revendications 1 à 4, 6 ou 7 ou composition suivant l'une quelconque des revendications 5 à 7, dans laquelle la source de glucides comprend une source de fibres alimentaires ayant un rapport des fibres solubles aux fibres insolubles d'approximativement 1:3.
- 5 9. Utilisation suivant l'une quelconque des revendications 1 à 4, 6, 7 ou 8 ou composition suivant l'une quelconque des revendications 5 à 8, dans laquelle les triglycérides à chaîne longue sont choisis de manière à fournir un rapport des acides gras n-6 aux acides gras n-3 compris dans l'intervalle de 4:1 à 10:1.

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